FORM PTO-1390 (REV 10-94) U.S. Dept. of Commerce and Patent and Trademark Office **TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371**		ATTORNEY'S DOCKET NUMBER: **P40.2-9585**
		U.S. APPLICATION NO. (If known): **09/701807**
INTERNATIONAL APPLICATION NO.: **PCT/AU99/00422**	INTERNATIONAL FILING DATE (dd/mm/yy): **31/05/99**	PRIORITY DATE CLAIMED (dd/mm/yy): **03/06/98**
TITLE OF INVENTION: **PRE-FILLED CONTAINER**		
APPLICANT(S) FOR DO/EO/US: **POPOVSKY, FRANK ALEXANDER**		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.

2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.

3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).

4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.

5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International bureau).
   b. ☒ has been transmitted by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States receiving Office (RO/US).

6. ☐ A translation of the International Application into English (35 U.S.C. 371 (c)(2)).

7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.

8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).

9. ☐ An oath or declaration of the inventor (35 U.S.C. 371(c)(4)).

10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.29 and 3.31 is included.

13. ☐ A **FIRST** preliminary amendment. Please enter the amendment before fee calculation.
    ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.

14. ☐ A substitute specification.

15. ☐ A change of power of attorney and/or address letter.

16. ☒ Other items or information: Constructive Petition for Extention of Time and Fee Authorization Pursuant to 37 C.F.R. 1.136(a)(3) and Correspondence Address of Law Firm

17. ☐ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492(A)(1)-(5)): *(select the appropriate one of the following fees)*		
Search Report has been prepared by the EPO or JPO ..... $ 930.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) ..... $ 490.00		
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) ..... $ 750.00		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... $ 1,070.00		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Articles 33(2)-33(4) ..... $ 98.00	1070.00 $	
ENTER APPROPRIATE BASIC FEE AMOUNT =		
Surcharge of $130.00 for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	- 20 =		x $ 22.00	$330.00	
Independent Claims	- 3 =		x $ 82.00	$	
Multiple Dependent Claims (if applicable)			+ $ 270.00	$	
TOTAL OF ABOVE CALCULATIONS =				$	
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must be filed also. (Note 37 CFR 1.9, 1.27, 1.28).				$	
SUBTOTAL =				$	
Processing fee of $130.00 for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$	
TOTAL NATIONAL FEE =				$1400.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). $40.00 per property				$	
TOTAL FEES ENCLOSED =				$	
				Amount to be: Refunded	$
				Charged	$

a. ☒ A check in the amount of $1400.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees is enclosed. A duplicate copy of this sheet is enclosed.

c. ☐ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 22-0350.

By: _____
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#3

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	POPOVSKY, Frank Alexander
Filed:	December 1, 2000
US Serial No.:	*not assigned yet*
For:	PRE-FILLED CONTAINER

Box Non-Fee Amendment
Assistant Commissioner for Patents
Washington, DC 20231

Docket No: P40.2-9585

PRELIMINARY AMENDMENT

Dear Sir:

Before calculating the filing fee please enter the following amendments.

In The Claims:

4.(Amended) A pre-filled plastic syringe are claimed in [any one of claims] claim 1 [to 3] wherein the closure is located wholly within the needle fitting of the syringe.

5.(Amended) A pre-filled plastic syringe as claimed in [any one of claims] claim 1 [to 4] wherein the wall portion is made of such material and is of such thickness that it may be punctured readily.

6.(Amended) A pre-filled plastic syringe as claimed in [any one of claims] claim 1 [to 5] wherein the needle fitting includes a hallow truncated cone, the interior of which is in liquid communication with the interior of the barrel once the seal created by the closure is broken.

7.(Amended) A pre-filled plastic syringe as claimed in [any one of claims] claim 1 [to 6] wherein the needle fitting is in the form of a truncated cone surrounded by a peripheral wall spaced from the cone.

8.(Amended) A pre-filled plastic syringe as claimed in [any of claims] claim 1 [to 7] wherein the closure is a separate component which is located within the barrel or within the needle fitting.

10.(Amended) A plastic pre-filled syringe as claimed in claim 9 wherein the wall portion is located at any position along the length of the inner wall of the [trunacated] truncated cone.

13.(Amended) A plastic pre-filled syringe as claimed in [any one of the previous claims] claim 1 in which the needle fitting is a luer lock needle fitting.

14.(Amended) A plastic pre-filled syringe as claimed in [any one of the previous claims] claim 1 in which the closure is puncturable by the rear needle of a double sided hypodermic needle.

15.(Amended) A plastic pre-filled syringe as claimed in [any one of the previous claims] claim 1 wherein the closure may be detached or in part broken away from the inner surface of the needle fitting or the barrel by utilizing a suitable tool.

16.(Amended) A plastic pre-filled syringe as claimed in [any one of claims] claim 10 [to 13] wherein the closure is a wall portion which extends across the internal passage of the truncated cone and is frangible attached to the inner surface thereof.

21.(Amended) A plastic pre-filled syringe as claimed in [any one of the previous claims] claim 1 which further includes a hollow closure opening conduit, a hypodermic needle and a needle support having an internal cavity, said hypodermic needle being attached at one end to the needle support and said needle support being positioned over the needle fitting, wherein a first end of said closure opening conduit is positioned within said internal cavity of the needle support

and a second end of the closure opening conduit is positioned within said needle fitting, the closure opening conduit being in liquid communication with the hypodermic needle and being of such length that movement of the needle support towards the moveable stopper end of the syringe will cause the closure opening conduit to break the seal provided by the closure.

27.(Amended) A plastic pre-filled syringe as claimed in [any one of claims] claim 21 [to 26] wherein said closure opening conduit is integral with and extends from the needle support.

28.(Amended) A plastic pre-filled syringe as claimed in [any one of claims] claim 21 [to 26] wherein said closure opening conduit is a separate component.

29.(Amended) A plastic pre-filled syringe as claimed in [any one of claims] claim 21 [to 28] wherein said closure opening conduit includes a central conduit and fins or ribs which extend outwardly therefrom.

30.(Amended) A plastic pre-filled syringe as claimed in [any one of claims] claim 21 [to 29] which further includes an overcap located over the hypodermic needle.

31.(Amended) A plastic pre-filled syringe as claimed in [any one of the previous claims] claim 1 wherein the filled and assembled syringe is hermetically sealed within a clear plastic wrapper.

32.(Amended) A method of using a plastic pre-filled syringe as claimed in [any one of claims] claim 21 [to 30] wherein said hypodermic needle is pushed or twisted onto the needle fitting whilst the product is hermetically sealed within a clear plastic wrapper.

34.(Amended) A pre-filled plastic syringe as claimed in [any one of the previous claims] claim 1 manufactured from a thermoplastics material

Please cancel claim 35.

REMARKS

The claim amendments are being made to remove the multiply dependent claims and otherwise conform the claims to United States practice. Claims 4-8, 10, 13-16, 21, 27-32 and 34 have been amended. Claim 35 has been canceled.

Respectfully submitted,

Vidas, Arrett & Steinkraus, P.A.
Attorneys of Record

Date: December 21, 2000

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PCT/AU99/00422
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PRE-FILLED CONTAINER

This invention concerns pre-filled containers, cartridges and syringes. It relates most particularly to a new form of syringe which can be pre-filled, fitted with a hypodermic needle and packaged as a ready to use product.

The applicant has previously proposed various designs for the manufacture of injection moulded plastic syringes. For example reference is made to the applicant's previous patent applications PCT/AU92/00007 and PCT/AU95/00723. In both of these prior cases the pre-filled syringe was sealed at the needle end by a closure in the form of a stem which was separable from the syringe. Whilst the applicant's previous proposals were significant improvements on pre-filled products which had been available piror to these developments, the use of a separable stem to seal the syringe gives rise to certain difficulties. First, a stem which protrudes from the end of the syringe is susceptible to accidental knocks – both in production and in use and this can lead to contamination or inadvertent opening of the unit. Secondly, in a system such as that described in PCT/AU95/00723 it is necessary to remove the stem from the needle fitting before a hypodermic needle can be attached. This means that the needle must be fitted in a separate step immediately prior to use. This can be inconvenient and there exists the possibility of contamination during the needle attachment operation.

It is an object of the present invention to provide a pre-filled syringe which is sealed in a manner which addresses, at least to some extent, the difficulties inherent in the prior units hereinbefore described.

In accordance with the present invention there is provided a pre-filled plastics syringe which includes:

(a) a barrel;

(b) a moveable stopper which seals the barrel at one end;

(c) a needle fitting which is integral with the barrel and which is located at the end of the syringe remote from the moveable stopper; and

(d) a closure which seals the syringe at its needling fitting end;

wherein an injectable liquid is housed within the barrel between the moveable stopper and the closure and wherein the closure is a wall portion located within the barrel and/or the needle fitting of the syringe.

Preferably, the needle fitting includes a hollow truncated cone, the interior of which is in liquid communication with the interior of the barrel. Most preferably, the needle fitting is in the form of a truncated cone surrounded by a peripheral wall spaced from the cone. An example of such a fitting is the "luer lock" needle fitting. A luer lock fitting incorporates a screw thread on the internal surface of the peripheral wall so the facilitate screw threaded engagement of a hypodermic needle onto the needle fitting. Hypodermic needles used in conjunction with luer lock needle fittings are attached at one end to a support which is conical, hollow and dimensioned to fit over and onto the central cone of the luer lock fitting. The base of the needle support includes a flange which is shaped to engage with the screw thread on the internal surface of the peripheral wall so that twisting of the hypodermic needle relative to the needle fitting facilitates engagement.

It is most preferred that the syringe of this invention utilise a luer lock needle fitting and that the syringe be used in conjunction with a hypodermic needle attached to a conical support as described above.

The closure may be a separate component located within the barrel or needle fitting such as by a friction fit or other suitable means. In such case it is preferred that the closure be made of such material and be of such thickness that it may be punctured readily.

However, the closure is preferably a wall portion which is frangibly connected to the inner surface of the barrel or to the inner surface of the needle fitting and which extends across the opening in the barrel or needle fitting. Most preferably the closure is located wholly within the needle fitting of the syringe. In the embodiment of the invention where the needle fitting includes a hollow truncated cone in liquid communication with the interior of the barrel it is preferred that the closure be an integral wall portion which is connected to the inner surface of the cone and extends across its opening. In this embodiment of the invention the wall portion can be located at any position along the inner wall of the needle fitting. Preferably it is frangibly attached to the inner surface of the truncated

cone and located at least 2.0 mm and most preferably at least 4.0 mm from the open end of the truncated cone so to reduce the prospect of the wall portion being broken away from the inner wall and (thus breaking the seal created by the wall portion) inadvertantly.

In order that the syringe may be opened readily when it is desired to express the injectable liquid it is desirable that the closure either be puncturable by the rear needle of a standard double sided hypodermic needle (in which case the closure is positioned close to the open end of the needle fitting) or alternatively that it be frangible so that it may be detached or in part broken away from the inner surface of the truncated cone or the barrel by utilizing a suitable tool.

In a particularly preferred embodiment of the invention the syringe includes a truncated conical needle fitting and the closure is a wall portion which extends across the internal passage of the cone and is frangibly attached to the inner surface of the cone.

In this embodiment it is desirable that the wall portion include a circumferential weakened section at or adjacent to its connection to the inner surface of the cone. The weakened section thus creates a "tear line" along which the closure may be detached (at least in part) from the inner surface of the cone. Preferably the wall portion is between 0.8 mm to 1.5 mm in thickness except in the weakened section where it is preferably between 0.05 to 0.2 mm in thickness. Whilst it is possible to utilize a weakened section which extends all the way around the wall portion this is not preferred as the application of a force against the wall portion in such an embodiment might result in the complete separation of the closure from the needle fitting. Whilst this would not adversely affect the operation of the syringe it is considered undesirable to have the closure floating freely in the injectable liquid. Thus, it is preferred that the weakened section extend circumferentially through about 330 - 350° so that when the closure is broken away from the inner surface of the cone along the weakened section the closure will still remain attached to the inside of the needle fitting and will be able to hinge about that section at or adjacent to the inner surface of the cone which is not weakened.

The seal provided by the wall portion may be broken by applying a force against the wall portion. A tool which incorporates a push rod of smaller diameter from the internal diameter of the cone and which is of sufficient length to reach the wall portion may be utilized for this purpose. Preferably such a tool has a flat end face sized to contact most of the surface area of the closure. Once the closure is detached, a hypodermic needle may be attached to the needle fitting making the syringe ready for immediate use.

Alternatively, and most preferably where the closure is frangibly connected to the needle fitting, the pre-filled syringe of the invention also includes a hollow closure opening conduit, a hypodermic needle and a needle support having an internal cavity, said hypodermic needle being attached at one end to the needle support and said needle support being positioned over (but not fully engaged with) the needle fitting, wherein a first end of said closure opening conduit is positioned within said internal cavity and a second end of the closure opening conduit is positioned within said needle fitting, the closure opening conduit being in liquid communication with the hypodermic needle and being of such length that movement of the needle support towards the moveable stopper end of the syringe will cause the closure opening conduit to break the seal provided by the closure.

Desirably the length of the closure opening conduit is such that full engagement of the needle support on the needle fitting provides sufficient movement of the needle support (and hence the closure opening conduit) to break the seal provided by the closure.

Preferably the cavity in the needle support includes an end face in which there is a centrally disposed aperture. The hypodermic needle may be fitted and secured at one end within the aperture so that it extends away from the cavity. The closure opening conduit is preferably located within the cavity with the first end abutting the end face of the housing with the internal passage therein in alignment with the aperture in the end face of the needle support. The other end of the closure opening conduit is preferably adjacent to or abuts the surface of the closure. In this way, movement of the needle support towards the moveable stopper end of the syringe will cause the end face to press against the first end of

the closure opening conduit and in turn apply pressure to the closure. By moving the support fully onto the needle fitting the closure opening conduit will be moved sufficiently to break the frangible connection of the closure to the needle fitting and thus facilitate direct liquid communication from the barrel of the syringe to the hypodermic needle past the opened closure and through the closure opening conduit.

The closure opening conduit may be integral with and extend from the needle support but it is preferably a separate component.

Preferably the closure opening conduit includes a central conduit and fins or ribs which extend outwardly therefrom so to minimize the contact between the closure opening conduit and the inner surface of the needle fitting. This reduces friction between the surfaces. As an alternative other closure opening means may be utilised which does not incorporate a conduit but is simply shaped to allow liquid passage. For example the closure opening means might be a solid rod which is of smaller diameter than the smallest diameter of the passage in the needle fitting with guide ribs which are configured to contact the inner surface of the needle fitting.

Desirably the pre-filled syringe also includes an overcap placed over the hypodermic needle. A tamper evident band may be provided around the base of the overcap so that prior removal of the overcap can be recognised by absence of the band or by its fracture.

The embodiment of the invention utilizing a closure opening conduit provides significant advantages in ease of use and avoidance of contamination. In particular, it is possible to injection mould all of the components, assemble and fill the syringe in an aseptic environment. The filled and assembled syringe may also be hermetically sealed within a clear plastic wrap such as cellophane prior to delivering the product out of the clean environment.

The pre-filled product may be delivered to practitioners with the hypodermic needle in position over the needle fitting but not fully engaged. In use the hypodermic needle may be pushed or twisted onto the needle fitting whilst the product is still in the hermitically sealed package. The complete seating of the hypodermic needle onto the needle fitting causes the seal formed by the closure

to be broken so that when the package is opened removal of the hypodermic needle overcap (if present) provides an opened pre-filled syringe ready for use and not susceptible to contamination by the application of additional parts or products to the syringe after the package has been opened.

The pre-filled plastic syringe of the invention is preferably manufactured from a thermoplastics material such as polypropylene. Other suitable materials include translucent and transparent plastics such as PET, polyamides or TPX. Other suitable materials are well known to those skilled in the art.

Examples of the invention are now described by reference to particularly preferred embodiments of the invention in which pre-filled syringes are injection moulded, assembled and packaged in a sterile environment and available for immediate use. The embodiments are shown in the following drawings in which:-

Figure 1 is a schematic diagram illustrating a pre-filled syringe packaged within an outer wrapper;

Figure 2 is a schematic diagram illustrating the pre-filled syringe shown in Figure 1 with the wrapper removed and prior to the syringe being opened;

Figure 3 is an end view of the pre-filled syringe shown in Figure 2 viewed from the plunger end;

Figure 4 is an enlarged schematic view of the needle fitting and closure of the pre-filled syringe shown in Figure 2;

Figure 5 is an enlarged view of the central cone of the needle fitting shown in Figure 4 and the associated closure;

Figure 6 is a schematic diagram illustrating the needle fitting end of the pre-filled syringe shown in Figure 2 with the hypodermic needle and needle support positioned over the end of the needle fitting of the syringe but prior to full engagement;

Figure 7 is a schematic diagram illustrating the needle fitting and hypodermic needle assembly as shown in Figure 6, after the hypodermic needle and needle support have been positioned firmly onto the needle fitting of the syringe;

Figure 8 is a schematic diagram illustrating the needle fitting end of the pre-filled syringe and the passage through which the injectable liquid can flow once the closure has been opened;

Figure 9 is a schematic representation of the closure opening conduit;

Figure 10 is a cross sectional view of a removable band intended for use in holding an overcap in position over the hypodermic needle prior to use;

Figure 11 is a schematic diagram illustrating an alternative embodiment of the invention utilising a double sided hypodermic needle;

Figure 12 is a schematic representation of the needle fitting end of the pre-filled syringe illustrated in Figure 11;

Figure 13 is a schematic diagram of the end of the truncated cone in the needle fitting illustrated in Figure 12; and

Figure 14 is a schematic representation of the double sided hypodermic needle with support and overcap.

Figure 1 is a schematic representation which illustrates how a preferred embodiment of the invention might be presented for distribution to doctors and other medical practitioners. The pre-filled syringe 1 is preferably manufactured by injection moulding all of the components in an aseptic environment, assembling and filling the syringe in the aseptic environment and sealing it within an outer wrapper 17.

The syringe 1 which is illustrated without the protective packaging in Figure 2, includes a barrel 1a and a plunger rod 2 affixed to a moveable stopper 3. Moveable stopper 3 seals the barrel at one end - the other end of the barrel being sealed by a closure 9 which is integral with a central truncated cone 13a of the needle fitting 13 at the other end of the syringe. The barrel 1a is filled with an injectable liquid 10 and this liquid is housed within the barrel 1a between moveable stopper 3 and closure 9.

An hypodermic needle 5 is secured to needle support 7. Needle support 7 includes an internal cavity 7a (best seen in Figure 6) and is positioned over the end of truncated cone 13a of the needle fitting 13. Hypodermic needle 5 is hollow and is in liquid communication with cavity 7a.

A hollow closure opening conduit in the nature of a separate tube 21 (again seen better in Figure 6) is positioned between needle support 7 and closure 9 and the use of this tube in conjunction with needle support 7 in detaching closure 9 is described below.

Hypodermic needle 5 is protected by an overcap 6 which is held in position by a circumferential band 4 which is shown in full detail in Figure 10.

The needle fitting 13 also includes an outer peripheral wall 15.

Figure 3 illustrates the syringe from the plunger rod end of the syringe, showing thumb press 12, finger support flanges 16 and gripping ribs 18. These features are shown simply to exemplify a particular embodiment of the invention but it will be appreciated that any type of plunger rod or moveable stopper mechanism, as known in the art, would be adequate for the purposes of the present invention.

Figure 4 illustrates the needle fitting end of the pre-filled syringe shown in Figure 2. The needle fitting includes a central truncated cone 13a and a peripheral outer wall 15. This is in the nature of a standard "luer lock" type needle fitting and is thus suitable for use in conjunction with a standard hypodermic and needle support of the type as shown in Figure 2. The peripheral wall 15 includes a spiral rib 20 which facilitates screw threaded engagement of needle support 7 onto the needle fitting 13. The needle fitting 13 has an opening 22 between peripheral wall 15 and central truncated cone 13a.

Different from a standard luer lock is the provision of a closure 9 in the form of an integral end wall portion located within the central truncated cone 13a.

The closure 9 whilst being integral with the inner surface of central truncated cone 13a is frangibly connected thereto as is better shown in Figure 5. Adjacent to the inner surface of truncated cone 13a closure 9 includes a tear line 8 being a circumferential portion of reduced thickness such that application of a force against closure 9 towards the moveable stopper end of the pre-filled syringe will cause the closure to tear away from the inner surface of truncated cone 13a along the tear line 8 of reduced thickness. In the embodiment shown the syringe is made from polypropylene and closure 9 is about 1.2 mm in thickness. The tear line is about 0.1 mm in thickness. Preferably tear line 8 does not extend around

the full circumference of closure 9 so that when a force is applied against the closure, at least some part of the closure will remain attached to the inner surface of truncated cone 13a so to leave the closure 9 attached to a portion of the inner surface of truncated cone 13a. The diameter of the inner passage of central truncated cone 13a is slightly larger on the barrel side of the closure 9 so to accommodate the closure when it is detached and folded back by tube 21.

The operation of the syringe is shown in more detail in Figures 6, 7 and 8. In Figure 6, the needle fitting end of the syringe is shown with closure 9 sealing the syringe. This is how the product would be supplied to end users. Needle support 7 is positioned over the central truncated cone 13a but the flange 7b of needle support 7 has not been engaged with the screw thread portion 20 of the peripheral wall 15. Tube 21 is located with a first end in abutment against the end of cavity 7a and with the other end in abutment against the face of closure 9. Tube 21 has a central passage 21a which is aligned so that it is in direct fluid communication with the passage 5a in hypodermic needle 5. Tamper indicating band 4 holds overcap 6 in position.

Figure 7 shows the needle fitting end of the pre-filled syringe after part of closure 9 has been detached from the inner surface of central truncated cone 13a. Preferably, this is achieved by applying a force to overcap 6 or circumferential band 4 in the direction of the moveable stopper end of the pre-filled syringe. This force will in turn move the needle support 7 further onto truncated cone 13a. To engage the screw thread 20 it is preferred that the force be used in conjunction with a twisting action so to screw the needle support 7 onto central cone 13a and towards the moveable stopper end of the syringe. This movement of support 7 causes a force to be applied to tube 21 which in turn applies a force to closure 9 causing it to tear away from the inner surface of central truncated cone 13a along tear line 8. In the preferred embodiment shown in Figure 7 the tear line 8 does not extend about the full circumference of the closure and thus it hinges to one side as can be clearly seen in Figure 7. Preferably tube 21 is chamfered at the end. This facilitates easy insertion of tube 21 into the truncated cone 13a when the product is being assembled but it also means that the tube 21 is less likely to completely detach the closure 9 from the

inner surface of truncated cone 13a. The opened closure 9 is held between the inner surface of truncated cone 13a and the outer surface of tube 21 once needle support 7 has been firmly engaged on needle fitting 13.

In Figure 8 the needle fitting end of pre-filled syringe 1 is shown ready for use. Tamper evident band 4 has been removed together with overcap 6 (contrast with Figure 7). The injectable liquid 10 can now be expressed out of syringe 1 in the direction of the arrow shown in Figure 8 by moving plunger rod 2 towards the needle fitting end of the syringe. The liquid 10 will move in the direction of the arrow in Figure 8 through the passage 21a and thereafter through the hollow hypodermic needle 5.

Figure 9 is a schematic representation showing tube 21 and Figure 10 is an enlarged cross section of tamper evident band 4. This band includes an internal rib 14 and an end flange 14a adapted to clip around the flange 6a of overcap 6.

An alternative embodiment of the invention is shown in Figures 11 to 14. In this embodiment, similar features to those described with respect to the first embodiment of the invention are similarly numbered. The primary difference between the embodiment of the invention shown in Figures 11 to 14 to that shown in Figures 1 to 10, concerns the position of closure 9 and the use of a double sided hypodermic needle.

Turning to Figure 11, there is shown a pre-filled syringe 1 which has a barrel 1a, a plunger rod 2 and a moveable stopper 3. Needle fitting 13 includes a central truncated cone 13a and a peripheral wall 15. The hypodermic needle 5 is fitted to a needle support 7. In contrast to the embodiment shown in Figures 1 to 10, the hypodermic needle 5 extends through the needle support 7 and has a sharpened end 5b located within cavity 7a. When the product is assembled and filled, the sharpened end 5b of the hypodermic needle 5 is located close to but not in contact with closure 9.

The needle fitting 13 and central truncated cone 13a are shown in greater detail in Figures 12 and 13. In order to ensure proper puncture of closure 9 by the sharpened end 5b of hypodermic needle 5 when the needle support 7 is fitted fully onto needle fitting 13, it is important that closure 9 be located close to the

end of central cone 13a. Whilst it may be located at the very end of central cone 13a, it is preferred that it be located a short distance within the cone, e.g. 0.5 mm from the end of cone 13a.

It will be appreciated that in use, securement of needle support 7 fully onto needle fitting 13 will cause movement of the sharp end 5b of hypodermic needle 5 towards and through closure 9 thus breaking the seal formed by closure 9 so that the injectable liquid 10 may be expressed from the syringe in similar manner to that described with respect to the first embodiment.

Figure 14 is an enlarged representation of hypodermic needle 5, needle support 7 and overcap 6.

It will be evident from the foregoing that the preferred embodiments of the invention as illustrated and described above can be manufactured, assembled and sealed within a wrapper all in an aseptic or clean environment. This product may be transported and stored with minimal risk of contamination and the wrapper can protect the syringe from any contamination and be removed only when the syringe is ready for use. As the mechanism for opening the syringe is activated by engaging the needle support 7 onto the needle fitting 13 there is no need for the needle fitting nor the needle support to be exposed to the environment and possible contamination prior to use. The consequent advantages in ease of use will be plain to those skilled in the art.

Various modifications and/or additions may be made to the embodiment hereinbefore described without departing from either the spirit or ambit of the present invention as defined in the following claims.

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Received 2 February 2000

CLAIMS:

1. A pre-filled plastic syringe which includes:

(a) a barrel;

(b) a moveable stopper which seals the barrel at one end;

(c) a needle fitting which is integral with the barrel and which is located at the end of the syringe remote from the moveable stopper; and

(d) a closure which seals the syringe at its needling fitting end;

wherein an injectable liquid is housed within the barrel between the moveable stopper and the closure and wherein the closure is a wall portion located within the barrel and/or the needle fitting of the syringe.

2. A pre-filled plastic syringe as claimed in claim 1 wherein the wall portion is frangibly connected to the inner surface of the barrel or to the inner surface of the needle fitting.

3. A pre-filled plastic syringe as claimed in claim 2 wherein the wall portion extends across and is located within the opening of the barrel or of the needle fitting.

4. A pre-filled plastic syringe as claimed in any one of claims 1 to 3 wherein the closure is located wholly within the needle fitting of the syringe.

5. A pre-filled plastic syringe as claimed in any one of claims 1 to 4 wherein the wall portion is made of such material and is of such thickness that it may be punctured readily.

6. A pre-filled plastic syringe as claimed in any one of claims 1 to 5 wherein the needle fitting includes a hollow truncated cone, the interior of which is in liquid communication with the interior of the barrel once the seal created by the closure is broken.

7. A pre-filled plastic syringe as claimed in any one of claims 1 to 6 wherein the needle fitting is in the form of a truncated cone surrounded by a peripheral wall spaced from the cone.

8. A pre-filled plastic syringe as claimed in any one of claims 1 to 7 wherein the closure is a separate component which is located within the barrel or within the needle fitting.

9. A plastic pre-filled syringe as claimed in claim 1 wherein the needle fitting includes an open ended hollow truncated cone the interior of which is in liquid communication with the interior of the barrel once the seal created by the closure is broken and the closure is an integral wall portion which is connected to the inner surface of the truncated cone and extends across its opening.

10. A plastic pre-filled syringe as claimed in claim 9 wherein the wall portion is located at any position along the length of the inner wall of the trunacated cone.

11. A plastic pre-filled syringe as claimed in claim 10 in which the closure is a wall portion which is frangibly attached to the inner surface of the truncated cone and located at least 2.0 mm from its open end.

12. A plastic pre-filled syringe as claimed in claim 10 wherein the wall portion is frangibly attached to the inner surface of the truncated cone and located at least 4.0 mm from its end.

13. A plastic pre-filled syringe as claimed in any one of the previous claims in which the needle fitting is a luer lock needle fitting.

14. A plastic pre-filled syringe as claimed in any one of the previous claims in which the closure is puncturable by the rear needle of a double sided hypodermic needle.

15. A plastic pre-filled syringe as claimed in any one of the previous claims wherein the closure may be detached or in part broken away from the inner surface of the needle fitting or the barrel by utilising a suitable tool.

16. A plastic pre-filled syringe as claimed in any one of claims 10 to 13 wherein the closure is a wall portion which extends across the internal passage of the truncated cone and is frangibly attached to the inner surface thereof.

17. A plastic pre-filled syringe as claimed in claim 16 wherein said wall portion includes a circumferential weakened section at or adjacent to its connection to the inner surface of the truncated cone.

18. A plastic pre-filled syringe as claimed in claim 17 wherein said wall portion is between 0.8 mm to 1.5 mm in thickness except in the weakened section where it is between 0.05 mm and 0.2 mm in thickness.

19. A plastic pre-filled syringe as claimed in claim 18 wherein said weakened section does not extend all the way around the wall portion.

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20. A plastic pre-filled syringe as claimed in claim 19 wherein the weakened section extends circumferentially through between 330 to 350° such that when the closure is broken away from the inner surface of the needle fitting along the weakened section the closure will remain attached to the inner surface of the needle fitting and will be able to hinge about that section at or adjacent to the inner surface of the needle fitting which is not weakened.

21. A plastic pre-filled syringe as claimed in any one of the previous claims which further includes a hollow closure opening conduit, a hypodermic needle and a needle support having an internal cavity, said hypodermic needle being attached at one end to the needle support and said needle support being positioned over the needle fitting, wherein a first end of said closure opening conduit is positioned within said internal cavity of the needle support and a second end of the closure opening conduit is positioned within said needle fitting, the closure opening conduit being in liquid communication with the hypodermic needle and being of such length that movement of the needle support towards the moveable stopper end of the syringe will cause the closure opening conduit to break the seal provided by the closure.

22. A plastic pre-filled syringe as claimed in claim 21 wherein the length of the closure opening conduit is such that full engagement of the needle support on the needle fitting provides sufficient movement of the closure opening conduit to break the seal provided by the closure.

23. A plastic pre-filled syringe as claimed in claim 22 wherein the cavity in the needle support includes an end face in which there is a centrally disposed aperture.

24. A plastic pre-filled syringe as claimed in claim 23 wherein the hypodermic needle is fitted and secured at one end within the aperture in the needle support and extends away from the cavity.

25. A plastic pre-filled syringe as claimed in claim 24 wherein the closure opening conduit is located within the cavity with the first end abutting the end face of the cavity with the internal passage therein in alignment with the aperture in the end face of the needle support.

26. A plastic pre-filled syringe as claimed in claim 25 wherein one end of the closure opening conduit is adjacent to or abuts the surface of the closure.

27. A plastic pre-filled syringe as claimed in any one of claims 21 to 26 wherein said closure opening conduit is integral with and extends from the needle support.

28. A plastic pre-filled syringe as claimed in any one of claims 21 to 26 wherein said closure opening conduit is a separate component.

29. A plastic pre-filled syringe as claimed in any one of claims 21 to 28 wherein said closure opening conduit includes a central conduit and fins or ribs which extend outwardly therefrom.

30. A plastic pre-filled syringe as claimed in any one of claims 21 to 29 which further includes an overcap located over the hypodermic needle.

31. A plastic pre-filled syringe as claimed in any one of the previous claims wherein the filled and assembled syringe is hermetically sealed within a clear plastic wrapper.

32. A method of using a plastic pre-filled syringe as claimed in any one of claims 21 to 30 wherein said hypodermic needle is pushed or twisted onto the needle fitting whilst the product is in a hermetically sealed package.

33. A method as claimed in claim 32 wherein the movement of the hypodermic needle onto the needle fitting causes the closure opening conduit to break the seal provided by the closure.

34. A pre-filled plastic syringe as claimed in any one of the previous claims manufactured from a thermoplastics material.

35. A plastic pre-filled syringe substantially as hereinbefore described with reference to what is shown in any one of the drawings.

FIG 1

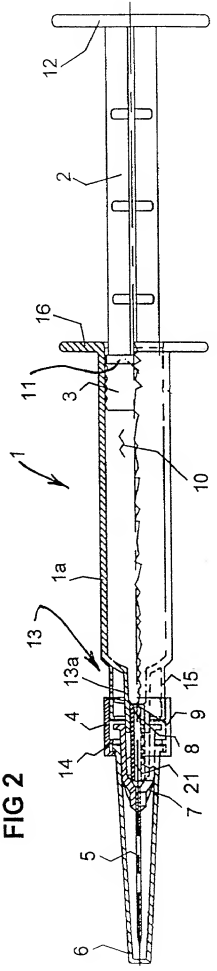

FIG 2

FIG 4

FIG 5

FIG 3

FIG 6

FIG 7

FIG 8

FIG 9

FIG 10

FIG 14

FIG 12

FIG 13

FIG 11

COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC 119
AU	PP3878	June 3, 1998	☒ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

I hereby claim the benefit under Title 35 United States Code, §119(e) of any United States provisional application identified below.

U.S. APPLICATIONS	
APPLICATION NUMBER	U.S. FILING DATE
1.	
2.	

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATIONS(S) UNDER 35 U.S.C. §120

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2.	
PCT APPLICATIONS DESIGNATING THE U.S.	
PCT APPLICATION NO.	PCT FILING DATE
3. PCT/US99/00422	31 May 1999

I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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PATENT/DESIGN PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: FRANK ALEXANDER POPOVSKY

Title: PRE-FILLED CONTAINER

Filed: ☐ Concurrently Herewith
☐ on _____
Serial No. _____

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Box PATENT APPLICATION
Assistant Commissioner for Patents
Washington, DC 20231

Docket No.: P40.2-9885

As a below named inventor of the subject matter of the above identified patent application, I hereby appoint the following attorneys to insert the docket no., filing date and application number of said application above when known; to prosecute this application and any application claiming priority therefrom; to execute any terminal disclaimers on behalf of assignee; and to transact all business in the Patent and Trademark Office connected therewith:

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all of VIDAS, ARRETT & STEINKRAUS, Professional Association, Suite 2000, 6109 Blue Circle Drive, Minnetonka, Minnesota 55343, USA, Telephone (612) 563-3000, and I hereby authorize them to act and rely on instructions from, and to communicate directly with, the firm or person which sent this case to VIDAS, ARRETT & STEINKRAUS unless or until I instruct VIDAS, ARRETT & STEINKRAUS in writing to the contrary.

Dated this 05TH day of NOVEMBER 2001,

(First inventor's signature) _____
(First inventor's name) FRANK ALEXANDER POPOVSKY

(Second inventor's signature) _____
(Second inventor's name) _____

(Third inventor's signature) _____
(Third inventor's name) _____

(Attach additional sheet with name(s) and signature(s) of fourth and subsequent inventors)
(Filing date, serial number and docket number may be left blank at time of signing)

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